510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k042307

B. Purpose for Submission: Notification of intent to manufacture and market the device: Seradyne ARCHITECT T-Uptake Calibrators (A-F) and ARCHITECT T-Uptake Controls (Low and High)

C. Analyte: NOT APPLICABLE

D. Type of Test: Calibrators and Controls

E. Applicant: Seradyne, Inc

F. Proprietary and Established Names: Proprietary - Seradyne ARCHITECT T-Uptake Calibrators (A-F) (Calibrator) **Established** - Calibrator. **Proprietary** - Seradyne ARCHITECT T-Uptake Controls (Low and High)

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1150 Calibrator.
   21 CFR 862.1660 Quality control material (assayed and unassayed).

2. Classification: Calibrator - Class II
   Control – Class I (reserved)

3. Product Code: Calibrator - JIT
   Control – JJX

4. Panel: Calibrator & Control –75

H. Intended Use:

1. Intended use(s): Architect T- Uptake Calibrators (A-F) - The Architect T-Uptake Calibrators are for the calibration of the ARCHITECT *i* system when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone (T4).

   Architect T- Uptake Controls - The Architect T-Uptake Controls are for the verification of the accuracy and precision of the ARCHITECT *i* when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone (T4).

2. Indication(s) for use: The Seradyne Architect T- Uptake Calibrators (A-F) - The Architect T-Uptake Calibrators are for the calibration of the ARCHITECT *i* system when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone Thyroxine (T4).

Architect T- Uptake Controls - The Seradyne Architect T-Uptake Controls are for the verification of the accuracy and precision of the ARCHITECT *i* when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone Thyroxine (T4).

3. Special condition for use statement(s): Not applicable

4. Special instrument Requirements: These controls and calibrators are intended for use on the Abbott Architect *i system.*

I. Device Description: The Seradyne Architect T- Uptake Calibrators (A-F) and Controls Are human serum containing Human Thyroxine Binding Globulin and a preservative used for the calibration and verification of the accuracy and precision of the Abbott Architect *i* System. The human serum used as the matrix for the calibrators and controls is tested and shown to be non-reactive for HBsAg, HIV, and anti-HCV by licensed tests.

J. Substantial Equivalence Information:

1. Predicate device name(s): AxSym T-Uptake Calibrators and Controls

2. Predicate K number(s): Calibrator – k934312 Control – k934312

3. Comparison with predicate:

Calibrator		
Item	**Device**	**Predicate**
Intended Use	Architect T-Uptake Calibrators (A-F) - The Architect T-Uptake Calibrators are for the calibration of the ARCHITECT *i* system when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone (T4).	AxSym T-Uptake Calibrators are for the calibration of the AxSym System when used for the quantitative determination of the total binding capacity of human serum or plasma for the thyroid hormone (T4).

Calibrator		
Item	**Device**	**Predicate**
Methodology	CMIA (Chemiluminescent Microparticle Immunoassay)	FPIA (Fluorescence Polarization Assay)
Platform	ARCHITECT System	AxSym System
Matrix	Human Serum with Preservative	Phosphate buffered protein (human)
Assay Sample Type	Serum/Plasma	Serum/Plasma
Control		
Item	**Device**	**Predicate**
Intended Use	The Architect T-Uptake Controls are for the verification of the accuracy and precision of the ARCHITECT *i* when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone (T4).	AxSym T-Uptake Controls are for the verification of the accuracy and precision of the AxSym System when used for the quantitative determination of the total binding capacity of human serum or plasma for thyroid hormone (T4).
Methodology	CMIA (Chemiluminescent Microparticle Immunoassay)	FPIA (Fluorescence Polarization Assay)
Platform	ARCHITECT System	AxSym System
Matrix	Human Serum with Preservative	Phosphate buffered protein (human)
Assay Sample Type	Serum/Plasma	Serum/Plasma

K. Standard/Guidance Document referenced (if applicable): FOD # 1247 - Abbreviated 510(k) Submission for In Vitro Calibrators; FOD# 2231 - Points to Consider Document on Assayed and Unassayed Quality Control Material.

L. Test Principle: Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Precision/Reproducibility: Not Applicable

a. Linearity/assay reportable range: Not Applicable

b. Traceability (controls, calibrators, or method):

Calibrator A contains Thyroxine Binding Globulin (TBG) – stripped Human Serum with Sodium Azide as a preservative. Calibrator A is then verified with the ARCHITECT *i* T-Uptake assay by comparison to the Master Calibrator on the ARCHITECT System. Calibrators B – F contains working stock of Calibrator A by adding calculated amounts of TBG Working Stock. The various levels are then compared and adjusted to a Master Calibrator on the ARCHITECT System. The kit calibrators must be within 2% of the Master calibrator.

Controls - Controls contain TBG in TBG stripped serum with sodium azide added as a preservative. Controls are manufactured by adding calculated amounts of TBG working stock to aliquots of Calibrator A. The various levels are compared and adjusted to Master Controls on the ARCHITECT *i* System.

The following statement taken from the Abbott AxSym t-update package insert describes the traceability of the AxSym T-uptake calibrators. “Abbott has developed an internal reference measure that generates a calibration curve designed to measure the binding capacity of human serum for T4. The linear response is based upon the millipolarization values obtained for a buffer with no binding capacity and a normal human serum pool, assigned a value of 1.0 T-Uptake unit. Abbott maintains a set of internal rare primary calibrators, which represent different levels of T4 binding capacity, and also T-Uptake ratios, less and greater than the normal pool. The kit calibrators are manufactured and signal matched at each level to the internal reference standards.”
With regard to stability under opened conditions, the calibrators and controls are liquid formulations, ready for use as packaged. The calibrators and controls are stored at 2 to 8 ^{o}C and are formulated with an antimicrobial agent. Stability studies were

designed to establish initial shelf life at the intended storage (2 to 8 ^{o}C) based on accelerated and real time data.

c. *Detection limit:* Not applicable

d. *Analytical specificity:* Not applicable

e. *Assay cut-off:* Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:* NOT APPLICABLE

   b. *Matrix comparison:* Not applicable

3. Clinical studies:
   a. *Clinical sensitivity:* Not applicable

   b. *Clinical specificity:* Not applicable

   c. *Other clinical supportive data (when a and b are not applicable):* Not applicable

4. Clinical cut-off: Not applicable

5. Expected values/Reference range: Not applicable

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.